B. Amendments to the Claims:

The following Listing of Claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

A listing of the claims is set forth below and is intended to replace all prior claims submitted in this application. In the claims presented herein, claim 1 is amended.

The above amendment is believed to obviate all rejections in the above-mentioned Office Action.

1. (Currently amended) A transdermal drug delivery composition ~~comprising~~ consisting essentially of

(a) a copolymer comprising

(i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and

(ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fetanyl.

2. (Original) The composition of claim 1 wherein the A monomer is selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate.

3. (Original) The composition of claim 1 wherein the A monomer is isooctyl acrylate.

4. (Original) The composition of claim 1 wherein the B monomer is selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate,

tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof.

5. (Original) The composition of claim 1 wherein the B monomer is 2-hydroxyethyl acrylate.

6. (Original) The composition of claim 5 wherein the copolymer comprises from about 5% to about 45% of 2-hydroxyethyl acrylate by weight based on the total weight of all monomers in the copolymer.

7. (Original) The composition of claim 1 wherein the copolymer further comprises a macromonomer.

8. (Original) The composition of claim 7 wherein the macromonomer is a functionally terminated polymethylmethacrylate.

9. (Original) The composition of claim 7 wherein the copolymer contains from about 1% to about 6% of macromonomer by weight based on the total weight of all monomers in the copolymer.

10. (Original) The composition of claim 1 wherein the composition further comprises a delivery enhancing adjuvant.

11. (Original) The composition of claim 10 wherein the delivery enhancing adjuvant is selected from the group consisting of alkane polyols, fatty acids, fatty acid esters, fatty alcohols, terpenes, C_5-C_{18} alkyl esters of a carboxylic acid, and mixtures thereof.

12. (Original) The composition of claim 10 wherein the delivery enhancing adjuvant is selected from the group consisting of ethyl oleate, isopropyl myristate, glycerol,

tetraglycol, methyl laurate, N,N-dimethyldodecylamine N-oxide, limonene, terpineol, tetraethylene glycol, menthol, and mixtures thereof.

13. (Previously presented) The composition of claim 10 wherein the concentration of the delivery enhancing adjuvant is from about 5% to about 40% by weight based on the total weight of the composition.

14. (Previously presented) The composition of claim 34 wherein the skin permeation enhancer is tetraglycol.

15. (Previously presented) The composition of claim 34 wherein the skin permeation enhancer is methyl laurate.

16. (Original) The composition of claim 1 wherein the concentration of fentanyl in said transdermal drug delivery composition is from about 12% to about 24% by weight.

17. (Original) The composition of claim 7 wherein the copolymer comprises from about 50 to about 94% isooctyl acrylate, about 5% to about 40% 2-hydroxyethyl acrylate, about 1% to about 6% macromonomer, and 0% to about 20% vinyl acetate by weight.

18. (Original) The composition of claim 7 wherein the copolymer comprises from about 52% to about 60% isooctyl acrylate, about 35% to about 40% 2-hydroxyethyl acrylate, about 1% to about 4% macromonomer, and 0% to about 10% vinyl acetate by weight.

19. (Original) The composition of claim 17 wherein the concentration of fentanyl is from about 12% to about 22% by weight, wherein the composition further comprises about 15% to about 35% by weight of a permeation enhancer selected from the group consisting of methyl laurate, tetraglycol, and mixtures thereof.

20. (Original) The composition of claim 19 wherein the concentration of fentanyl is from about 12% to about 17% by weight and the concentration of methyl laurate is from about 20% to about 35% by weight.

21. (Original) The composition of claim 19 wherein the concentration of fentanyl is from about 15% to about 22% by weight and the concentration of tetraglycol is from about 15% to about 25% by weight.

22. CANCELLED

23. (Previously presented) A pressure sensitive adhesive composition for the transdermal delivery of fentanyl comprising

(a) an acrylate polymer;

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and

(c) a delivery enhancing adjuvant selected from the group consisting of methyl laurate, tetraglycol, and mixtures thereof;

wherein the composition is substantially free of undissolved fentanyl.

24. (Original) The composition of claim 23 wherein the concentration of delivery enhancing adjuvant is from about 5% to about 40% by weight based on the total weight of the composition.

25. (Previously presented) The composition of claim 23 wherein the acrylate polymer comprises:

(a) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and

(b) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer.

26. (Original) The composition of claim 25 wherein the B monomer is selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N,N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, N-vinyl pyrrolidone and mixtures thereof.

27. (Original) A device for the transdermal delivery of fentanyl comprising a backing and a composition according to claim 1, said composition being adhered to one surface of the backing.

28. (Original) A method of treating in a mammal a condition capable of treatment by fentanyl comprising the steps of:

(a) providing a composition according to claim 1;

(b) placing the composition on the skin of a mammal; and

(c) allowing the composition to remain on the skin for a time sufficient to establish or maintain a therapeutically effective blood level of fentanyl in the mammal.

29. (Original) A method of providing analgesia to a mammal comprising the steps of:

(a) providing a composition according to claim 1;

(b) placing the composition on the skin of a mammal; and

(c) allowing the composition to remain on the skin for a time sufficient to establish or maintain an analgesically effective blood level of fentanyl in the mammal.

30. (Previously presented) A method of providing sustained analgesia to a mammal comprising delivering fentanyl to a mammal via a transdermal drug delivery device in an amount of about 0.5 to about 5.0 mg/day thereby causing the serum concentration of fentanyl in the mammal to be about 0.2 to about 10 ng/mL for a period of time from about 4 to about 14 days, wherein the device includes a composition comprising an acrylate polymer and about 8% to about 30% by weight fentanyl based on the total weight of the composition, wherein the composition is substantially free of undissolved fentanyl.

31. (Original) The method of claim 30 wherein the fentanyl is delivered in an amount of 0.5 to 2.5 mg/day, the serum concentration of fentanyl in the mammal is about 0.3 to about 4 ng/mL, and the period of time is from about 6 to about 8 days.

32. (Original) A device for the transdermal delivery of fentanyl comprising:

(a) a drug reservoir layer comprising the composition of claim 1;

(b) a rate controlling membrane adhered to one surface of the drug reservoir layer; and

(c) a skin contacting pressure sensitive adhesive layer adhered to the surface of the membrane that is opposed to the surface of the membrane in contact with the reservoir layer.

33. (Original) A device for the transdermal delivery of fentanyl comprising:

(a) a drug reservoir layer comprising the composition of claim 17;

(b) a rate controlling membrane adhered to one surface of the drug reservoir layer; and

(c) a skin contacting pressure sensitive adhesive layer adhered to the surface of the membrane that is opposed to the surface of the membrane in contact with the reservoir layer.

34. (Previously presented) The composition of claim 10 wherein the delivery enhancing adjuvant is a skin permeation enhancer.

35. (Previously presented) A transermal drug delivery composition comprising:

(a) a copolymer comprising:

(i) one or more A monomers from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and

(ii) one or more ethylenically unsaturated B monomers copolymerizable with the acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-

diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxythyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl.

36. (Previously presented) A transdermal drug delivery composition comprising:

(a) a copolymer comprising:

(i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and

(ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl.

37. (Previously presented) A transdermal drug delivery composition comprising

(a) a copolymer comprising

(i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and

(ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer, wherein at least one B monomer is 2-hydroxyethyl acrylate; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl; and

wherein the drug delivery device delivers fentanyl to a mammal via a transdermal drug delivery device in an amount of about 0.5 to about 5.0 mg/day thereby causing the serum concentration of fentanyl in the mammal to be about 0.2 to about 10 ng/mL for a period of time from about 4 to about 14 days.

38. (Previously presented) A transdermal drug delivery composition comprising

(a) a copolymer comprising

(i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and

(ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein at least one B monomer 2-hydroxyethyl acrylate,; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and

(c) a delivery enhancing adjuvant selected from the group consisting of methyl laurate, tetraglycol,and mixtures thereof;

wherein the composition is substantially free of undissolved fentanyl.